

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH Office of Health Care Access

September 16, 2010

IN THE MATTER OF:

An Application for a Certificate of Need filed pursuant to Section 19a-639, C.G.S. by

Notice of Final Decision
Office of Health Care Access
Docket Number: 10-31577-CON

Hartford Hospital

Acquisition of a Computed Tomography Simulator

Karen T. Goyette Vice President, Strategic Planning Hartford Hospital 85 Seymour Street Hartford, CT 06102-5037

Dear Ms. Goyette:

This letter will serve as notice of the Final Decision of the Office of Health Care Access in the above matter as provided by Section 19a-639, C.G.S. On September 16, 2010, the Final Decision was rendered as the finding and order of the Office of Health Care Access. A copy of the Final Decision is attached hereto for your information.

By Order of the Office of Health Care Access Department of Public Health

Kimberly R. Martone Director of Operations

KRM: bac Enclosure



Office of Health Care Access Certificate of Need Application

Final Decision

Applicant:

Hartford Hospital

Docket Number:

10-31577-CON

Project Title:

Acquisition of a Computed Tomography Simulator

Project Description: Hartford Hospital ("Applicant" or "Hospital") is proposing to acquire a Computed Tomography simulator ("CT simulator") to be located at the Hospital's Helen and Harry Gray Cancer Center at Hartford Hospital, with an associated capital expenditure of \$999,414.

Nature of Proceedings: On July 21, 2010, the Office of Health Care Access ("OHCA") received a Certificate of Need ("CON") application from the Applicant for the above-referenced project.

A notice to the public concerning OHCA's receipt of the Applicant's Letter of Intent was published on April 19, 2010, in *The Hartford Courant*. OHCA received no response from the public concerning the Applicant's proposal.

Pursuant to Section 19a-639 of the Connecticut General Statutes ("C.G.S.") three individuals or an individual representing an entity with five or more people had until August 11, 2010, the twenty-first calendar day following the filing of the Applicant's CON application, to request that OHCA hold a public hearing on the Applicant's proposal. OHCA received no hearing requests from the public.

OHCA's authority to review, approve, modify, or deny this proposal is established by Section 19a-639, C.G.S. The provisions of this section, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

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FINDINGS OF FACT

- 1. The Applicant is an acute care general hospital located at 80 Seymour Street in Hartford, Connecticut. (March 25, 2010, Letter of Intent (LOI) Submission, page 1)
- 2. The Hospital's Department of Radiation Oncology delivers radiation treatments in the form of Image Guided Radiation Therapy ("IGRT"), Intensity Modulation Radiation Therapy ("IMRT"), Stereotactic Radiation Therapy ("SRT"), and conventional radiation oncology treatments. (March 25, 2010, Letter of Intent (LOI) Submission, page 8)
- 3. The Hospital also provides high dose rate ("HDR") and low dose rate ("LDR") Brachytherapy as well as Simulation and Treatment Planning services at the Helen and Harry Gray Cancer Center in Hartford and Avon. The Avon campus currently utilizes a CT Simulator very similar to the one the Hospital plans to acquire in this proposal. (March 25, 2010, Letter of Intent (LOI) Submission, page 8)
- 4. The Applicant provided the following list of CT scanners currently in use by location:

Table 1: Hartford Hospital's CT scanners

Location	Area	Available Imaging	Utilization		
Hartford Hospital, 80 Seymour Street Hartford, CT	Radiology	GE VCT 64 Slice GE Lightspeed Ultra 8 Slice	FY 2009 22,420 scans combined		
Hartford Hospital, 80 Seymour Street Hartford, CT	Emergency Department	GE Lightspeed Ultra 8 Slice	FY 2009 27,396 scans		
Hartford Hospital, 80 Seymour Street Hartford, CT	Helen and Harry Gray Cancer Center	Discovery LS 4 Slice	FY 2009 1,619 PET/CT scans		
Hartford Hospital, 80 Fisher Drive Avon, CT	Helen and Harry Gray Cancer Center	Toshiba Aquilion LB 16 Slice CT	5/1/2009 – 4/30/2010 205 CT simulation scans		

(June 10, 2010, Initial CON Application Submission, page 4)

5. The Hospital proposes to replace a conventional Philips simulator¹ with a Toshiba Aquilion 16 slice Large Bore CT Simulator² at the Helen and Harry Gray Cancer Center, Hartford campus location. (*June 10, 2010, Initial CON Application Submission, page 3*)

Maidstone Hospital, Maidstone, Kent ME16 9QO, UK)

¹ Conventional simulation uses machines that are capable of producing similar movements as treatment machines. The images created are essentially two dimensional and produce a limited number of axial slices to provide patient contours and tissue density information. (Source: Localization: conventional and CT simulation, GR Baker, Kent Oncology Centre, Maidstone Hospital, Maidstone, Kent ME16 9QQ, UK)
² CT simulators produce three dimensional images that can be combined with software to produce virtual simulations. (Source: Localization: conventional and CT simulation, GR Baker, Kent Oncology Centre,

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6. The Philips simulator became unusable during the first quarter of FY 2007 and was not repaired due to the equipment's age and technological limitations. (July 21, 2010, Completeness Response Submission, page 203)

- 7. Patients in the cancer center currently receive CT scans in the Radiology Department or the Emergency Department ("ED"). (June 10, 2010, Initial CON Application Submission, page 3)
- 8. The CT scanners in the Radiology Department and ED are heavily utilized for high volume procedures or images during day time hours and therefore, do not always permit as timely a service for cancer patients as would be indicated. The location of the scanners is less convenient and requires transportation of the patient, the treatment records and the treatment devices. (June 10, 2010, Initial CON Application Submission, page 3)
- 9. The Radiology Department and ED scanners are located a significant distance from the cancer center and therefore, require inconvenient travel for cancer center patients, who are frequently debilitated, and staff, including a team of technologists and physicists and at times a radiation oncologist. This causes stress for the patients and presents logistical challenges for the staff. (*June 10, 2010, Initial CON Application Submission, page 8*)
- 10. Additionally, the bore size of the CT scanners in the Radiology Department and ED limits the scanning of patients in the treatment position due to the size of the devices required and many larger patients cannot be treated in conventional small bore CT scanners. The large bore of the proposed scanner will eliminate these issues. (June 10, 2010, Initial CON Application Submission, page 3)
- 11. The proposed acquisition of a CT simulator in the cancer center will reduce the dependence on the Radiology and ED scanners and eliminate the need to transport patients, treatment records and treatment devices. (June 10, 2010, Initial CON Application Submission, pages 3)
- 12. A dedicated CT simulator in the cancer center will also allow the scan to be performed by radiation oncology staff in the treatment position with the appropriate radiation oncology customized immobilization devices, thus simulating the patient's actual treatment position. (June 10, 2010, Initial CON Application Submission, page 8)
- 13. CT scanning in the treatment position allows the radiation oncologist to contour selected soft tissue targets and avoidance structures so that precise 3 dimensional radiation therapy treatment planning can be undertaken. (June 10, 2010, Initial CON Application Submission, page 8)
- 14. The location and extent of the target volume and position of adjacent organs at risk ("OAR") is necessary for the successful implementation of conformal radiation therapy ("CRT") and IMRT. "The three dimensionality of virtual simulation is essential to visualize the coverage of the target volume and the avoidance of

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OARs in the highly complex treatment plans required for CRT and IMRT." (Baker, GR, "Localization: conventional and CT simulation," British Journal of Radiology, 2006 Sep;79 Spec No 1:S36-49)

- 15. Newer CT simulators offer innovative technologies that will aid in the delivery of highly focused radiation techniques such as stereotactic radiosurgery ("SRS"), SRT and gated radiation therapy. (June 10, 2010, Initial CON Application Submission, page 9)
- 16. SRT, SRS and gated radiation therapy utilize images taken in various phases of the respiratory cycle so that tumor tracking can assure accurate delivery of the focused radiation even while the patient breathes in and out resulting in tumor motion. A dedicated CT simulator can have parameters developed which allow individualized settings and protocols for imaging, which would not be possible in a busy diagnostic imaging department. (June 10, 2010, Initial CON Application Submission, page 9)
- 17. Various brachytherapy procedures, including breast brachytherapy and temporary HDR brachytherapy for cervical, endometrial and vaginal cancers, would also benefit from CT simulation for treatment planning. (June 10, 2010, Initial CON Application Submission, page 9)
- 18. An examination of cervical cancer treatment concluded that "CT simulation images more precisely defined the clinical target volume. This more accurate definition of the target volume and individualization of field delineation may potentially lead to an improved therapeutic ratio..." (June 10, 2010, Initial CON Application Submission, page 8 & 9; Marisa H. Finlay, MD., et al, "Use of CT simulation for treatment of cervical cancer to assess the adequacy of lymph node coverage of conventional pelvic fields based on bony landmarks," International Journal of Radiation Oncology, Biology, Physics, 2006 Jan 1;64(1):205-9.
- 19. CT Simulation has also been found to be beneficial in the treatment of breast cancer, as one study concluded that "...CT-based treatment planning generated the most successful plans for proper target coverage..." (June 10, 2010, Initial CON Application Submission, page 40; Raweewan Liengsawangwong, MD., et al, "Treatment optimization using Computed Tomography-delineated targets should be used for supraclavicular irradiation for breast cancer," International Journal of Radiation Oncology, Biology, Physics, 2007 Nov 1;69(3):711-5)
- 20. OHCA finds that a dedicated CT simulator equipped with radiation oncology hardware and software and located in the radiation oncology department will enhance patient care and satisfaction and ensure efficient and effective delivery of health care to patients in the cancer center.
- 21. The Hartford campus provided treatment to 622 radiation oncology patients in FY 2009 (see Table 3b).
- 22. The proposal will not change the patient population currently being served. (June 10, 2010, Initial CON Application Submission, page 4)

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23. The Hospital provided historical and projected CT scan volumes:

Table 3a: Hartford Hospital Historical and Projected CT Volume

	Actual Volume (Last 3 Completed FYs)			CFY Volume*	Projected Volume (First 3 Full Operational FYs)		
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Radiology IP	15,618	15,316	16,848	16,100	16,100	16,100	16,100
Radiology OP	5,129	4,926	5,572	5,100	5,100	5,100	5,100
ED	25,918	25,786	27,396	25,800	25,800	25,800	25,800
Total	46,665	46,028	49,816	47,000	47,000	47,000	47,000

Note: Fiscal year runs from Oct 1st through Sept 30th.

(June 10, 2010, Initial CON Application Submission, page 5)

Table 3b: Hartford Hospital Historical and Projected # of Radiation Oncology Patients
(Hartford Compus)¹

(Hartiord Ca	A	Actual Volume (Last 3 Completed FYs)			Projected Volume (First 3 Full Operational FYs		
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Radiation Oncology							
Patients	646	642	622	630	630	630	630

Note: Fiscal year runs from Oct 1st through Sept 30th.

(June 10, 2010, Initial CON Application Submission, page 6)

- 24. The slight drop in Radiation Oncology patient volume from FY 2007 to FY 2009 was due in part to a redistribution of patients to the Avon location (opened in late summer of 2008) and is projected to increase in FY 2010. (July 21, 2010, Completeness Response Submission, page 203)
- 25. The Applicant's projections with respect to the number of radiation oncology patients requiring scans are reasonable in light of the historical utilization.
- 26. Moreover, the volumes on the diagnostic scanners in the ED and Radiology department, as reflected in Table 3a, demonstrate that those are highly utilized scanners.
- 27. Accordingly, OHCA finds that the acquisition of a dedicated CT simulator in the cancer center will improve accessibility of care for the Hospital's patients.
- 28. The capital expenditure associated with the proposed acquisition of the CT Simulator is \$999,414. (June 10, 2010, Initial CON Application Submission, page 11)

^{*}Based on 7 months actual (October-April)

¹ Subset of Table 2a

^{*} Based on 9 months actual (October 2009-June 2010)

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29. The Applicant provided a summary of incremental gains/losses projected as a result of the CT simulator acquisition:

Table 4: Hartford Hospital's Financial Projections Incremental to the Project

· · · · · · · · · · · · · · · · · · ·	Fiscal Year				
Description	2011	2012	2013		
Incremental Revenue from Operations	0	0	0		
Incremental Total Operating Expense	\$99,831	\$249,662	\$252,662		
Incremental Gain/Loss	(\$99,831)	(\$249,662)	(\$252,662)		
Gain/(Loss) from Operations (with CON)	\$19,030,169	\$29,770,338	\$47,631,338		

Note: Hartford Hospital's fiscal year runs from Oct 1st through Sept 30th. (June 10, 2010, Initial CON Application Submission, page 15)

- 30. Incremental losses of (\$99,831) in FY 2011, (\$249,662) in FY 2012 and (\$252,662) in FY 2013 are projected as the result of the simulator acquisition. No additional revenue will be generated and the Hospital will incur depreciation and maintenance contract expenses.
- 31. Despite the incremental losses due to the CON proposal, the Hospital still projects overall gains from operations of \$19,030,169 in FY 2011, \$29,770,338 in FY 2012 and \$47,631,338 in FY 2013.
- 32. OHCA finds that although the Hospital is anticipating incremental losses as a result of the proposal, overall gains from operations are still projected for FY 2011-2013.
- 33. The Applicant reported the following payer mix based on patient population as follows:

Table 4: Current & Three-Vear Projected Paver Mix for the Applicant

		Year 1	Year 2	Year 3	
Payer Mix	FY 2010	FY 2011	FY 2012	FY 2013	
Medicare*	38%	38%	38%	38%	
Medicaid*	21%	21%	21%	21%	
CHAMPUS & TriCare	0%	0%	0%	0%	
Total Government	59%	59%	59%	59%	
Commercial Insurers*	39%	39%	39%	39%	
Uninsured	2%	2%	2%	2%	
Workers Comp.**					
Total Non-Government	41%	41%	41%	41%	
Total Payer Mix	100%	100%	100%	100%	

^{*}Includes managed care activity

34. The overall payer mix should not be affected by the approval of this proposal. (June 4, 2010, Initial CON Application Submission, page 20)

^{**}Workers Compensation is included in Commercial Insurers (June 10, 2010, Initial CON Application Submission, page 12)

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Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for Certificate of Need ("CON") proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

Hartford Hospital is an acute care general hospital located at 80 Seymour Street in Hartford, Connecticut. The Hospital is proposing to acquire a Computed Tomography simulator ("CT simulator") to be located at the Hospital's Helen and Harry Gray Cancer Center at Hartford Hospital, with an associated capital expenditure of \$999,414.

The current Phillips simulator at the cancer center in Hartford became unusable in 2007. [Finding 6]. Patients in the cancer center currently receive CT scans in the Radiology Department or ED. [Finding 7] However, the Radiology Department and ED scanners are highly utilized and may not always permit cancer patients to receive as timely a service as indicated. [Findings 8, 23 & 26] Additionally, the existing scanners may not accommodate certain treatment devices or larger patients. [Findings 10] Moreover, the transportation of the patient, treatment record and treatment devices can be logistically challenging for staff and stressful for patients. [Finding 9] OHCA finds that the proposal to acquire a CT simulator will improve access for patients and provide more efficient and effective treatment within the Helen and Harry Gray Cancer center.

A dedicated CT simulator in the cancer center will also allow the scan to be performed by radiation oncology staff in the treatment position with the appropriate radiation oncology customized immobilization devices, thus simulating the patient's actual treatment position. [Finding 12] CT simulation in the treatment position allows radiation oncologists to contour selected soft tissue targets and avoidance structures so that precise 3 dimensional radiation therapy treatment planning can be undertaken. [Finding 13] The location and extent of the target volume and position of adjacent OARs is necessary for the successful implementation of CRT and IMRT. [Finding 17] Additionally, CT simulation has also proven to be beneficial for various brachytherapy procedures, including breast brachytherapy and temporary HDR brachytherapy for cervical, endometrial and vaginal cancers. [Findings 17-19] Accordingly, OHCA finds that the technological advantages provided by use of the CT simulator will positively impact the quality of health care delivery to cancer patients at Hartford Hospital.

Although the Hospital anticipates incremental losses as a result of acquiring the CT simulator, overall operating gain projections remain positive in FY 2011, FY 2012 and FY 2013. The Hospital's utilization volumes and financial projections upon which the operating gains are based appear to be reasonable. Therefore, OHCA finds that the CON proposal is financially feasible.

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Order

Based on the foregoing Findings and Rationale, the Certificate of Need application of Hartford Hospital for the acquisition of a Computed Tomography ("CT") simulator, with an associated capital expenditure of \$999,414 is hereby **GRANTED**, subject to the following conditions:

- 1. Hartford Hospital shall submit to OHCA in writing the initial date of operation for the CT simulator acquired for use at the Helen and Harry Gray Cancer Center at Hartford Hospital.
- 2. Should the Applicant plan to operate the CT simulator at a location other than the Helen and Harry Gray Cancer Center at Hartford Hospital, the Applicant shall notify OHCA of the new location, no later than one month after the equipment's relocation.

Should the Applicant fail to comply with any of the aforementioned conditions, OHCA reserves the right to take additional action as authorized by law. All of the foregoing constitutes the final order of the Office of Health Care Access in this matter.

By Order of the Department of Public Health Office of Health Care Access

Japh. 16, 2010

Norma Gyle, R.N., Ph.D. OHCA Deputy Commissioner

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